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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,011

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Liecheng Zhang

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EXAMINER

KING, FELICIA C

ART UNIT

PAPER NUMBER

1794

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,011	<b>Applicant(s)</b> ZHANG ET AL.	
	<b>Examiner</b> FELICIA C. KING	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/06; 2/28/08</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "slightly yellowish" in claim 1 is a relative term which renders the claim indefinite. The term "slightly yellowish" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
3. Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the limitation "the resultant gel liquor" in line 6 of Claim 2. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 4 recites the limitation "the gel liquor" in line 9 of Claim 4. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 4 recites the limitation "the residue" in line 10 of claim 4. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 4 recites the limitation "the quality control" in lines 17-18 of Claim 4. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. **Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (US 5,703,211) in view of Harnack (US 2,557,871) and in further view of**

**National Organic Standards Board Technical Advisory Panel (“NOSB –TAP”) 2002  
“Gelatin: processing”.**

**Regarding Claim 1:** Taylor discloses hydrolyzed collagen from isinglass (which is a synonym for fish maw) in powder form having a moisture content below 6% but does not disclose where the powder has particle size of 80 - 200 mesh and does not explicitly disclose where the product is characterized as being transparent and slightly yellowish. However, Harnack discloses a dried gelatin stock which is capable of passing through a 100 mesh screen [col. 4, lines 31-38]. Further, the NOSB-TAP disclose the characterization of gelatin products as colorless or slightly yellow, and transparent [pg. 2, Properties].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Taylor, Harnack and “NOSB-TAP” before him or her to modify the product of Taylor to be capable of passing through a 100 mesh screen because at this mesh size the gelatin product is suitable or use in food products [Harnack, col. 3, lines 1-29; col. 4, lines 35-38]. Further, it would have been obvious to one having ordinary skill in the art that a collagen product that has been hydrolyzed and treated to form gelatin would be characterized as being colorless or slightly yellow, and transparent since these properties are shared by all gelatin products as disclosed by the NOSB-TAP.

**5. Claims 2, 3, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (US 5,703,211) in view of Harnack (US 2,557,871) ,and The National**

**Organic Standards Board Technical Advisory Panel ("NOSB –TAP") 2002**

**"Gelatin: processing" and in further view of Hadden (US 5,162,506).**

**Regarding Claim 2:** Taylor discloses a process of preparing a powdered product from isinglass (fish maw) by soaking cut up fish maw in acid at a temperature of 8°C to 20°C [col. 4, lines 4-10] and drying the resulting product to give a dried product [col. 4, lines 29-31] but does not disclose where the acid treated maws are washed, subjected to pressure of 0.3 -1kg/cm<sup>2</sup> at a temperature of 90°C - 120°C; or filtering the gel liquor. The "NOSB-TAP" discloses gelatin characterization as discussed above. However, Harnack discloses a process of making gelatin stock where after the collagen is subjected to hydrolyzation with an acid, the gelatin stock is washed to remove excess acid and to adjust the pH [col. 1, lines 47-51] and also discloses where the gelatinous liquid is removed, filtered, and subsequently dried [col. 2, lines 9-12]. However, Hadden discloses a process where collagen is subjected to temperature of about 115°C to 125°C in a pressure cooker and subsequently gelatinized [col. 9, lines 1-4].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Taylor, Harnack, "NOSB-TAP", and Hadden before him or her to subject the isinglass (fish maw) of Taylor to heat/pressure treatment because the application of heat causes gel formation and the application of pressure reduces the time required for gel formation. Further, filtering the gel liquor would have been an obvious step in order to remove insoluble materials and to aid in the ease of the drying process to obtain the characteristic low moisture content and solubility of gelatin ["NOSB-TAP" pg. 2 "Composition"].

Although Hadden does not explicitly disclose the pressure at the gelatinization was effected, it is well known in the art that pressure cookers operate at a range of 1 - 15 psi ( $0.0703 \text{ kg/cm}^2 - 1.05 \text{ kg/cm}^2$ ) and therefore the examiner has interpreted Hadden as reciting  $0.0703 \text{ kg/cm}^2 - 1.05 \text{ kg/cm}^2$ .

Further, regarding the range of pressure, one having ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Hadden, overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. *In re Malagari* 182 USPQ 549,553.

Further, regarding the range of temperatures one having ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Hadden, overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. *In re Malagari* 182 USPQ 549,553.

**Regarding Claim 3:** Taylor discloses a process of preparing a powdered product from isinglass (fish maw) as discussed above but does not disclose pulverizing dried fish maw. However, Harnack discloses comminuting the dried gelatin by using a hammer mill, resulting in gelatin which is capable of passing through a 100 mesh screen [col. 5, lines 30-34]. Hadden and NOSB-TAP disclose as discussed above.

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Taylor, Harnack, "NOSB-TAP", and Hadden before him or her to modify the method of Taylor to include using a hammer mill which pulverizes

Art Unit: 1794

the dried gelatin product because this would result in a finer gelatin particle size as indicated by Harnack.

**Regarding Claim 5:** Taylor discloses a process of preparing a powdered product from isinglass (fish maw) as discussed above but does not disclose where the acid treatment is with hydrochloric acid. Harnack discloses washing of collagen as discussed above. Hadden discloses pressure treatment as discussed above. However, NOSB-TAP discloses the characterization of gelatin as discussed above and further discloses using a food grade mineral acid such as hydrochloric acid to treat a collagen product in order to make gelatin [NOSB-TAP, pg 4].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Taylor, Harnack, "NOSB-TAP", and Hadden before him or her to modify the acid used to treat isinglass (fish maw) of Taylor for HCL in order to attain the desired material swelling of 2 -3 three times its normal volume which is indicative of hydrolyses of the collagen material and further it is well known that various food grade acids can be used to treat the collagen material [Fish gelatin process, pg 3] as desired.

**6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (US 5,703,211) in view of Harnack (US 2,557,871) and, The National Organic Standards Board Technical Advisory Panel ("NOSB –TAP") 2002 "Gelatin: processing" and in further view of Hadden (US 5,162,506), and McGuckian (US Patent 3,966,980), Robson (US 4,529,612), and Philips "Handbook of Hydrocolloids" Chap 4 pgs 69-70.**



**Regarding Claim 4:** Taylor discloses removing impurities, washing [col. 2, lines 5-10] and softening isinglass (fish maw) by soaking for 24 hours and bringing the pH to 3 at 8°C to 20°C [col. 4, lines 7-13] and drying the resulting product to give a moisture content of below 6% [col. 4, lines 29-31] as discussed above but does not disclose where the acid treated maws are washed until the pH rises to 6-7, causing gelatinization by placing the fish maws in a stainless steel jacketed pressure cooker, adding water to the cooker, applying a pressure of 0.5 kg/cm<sup>2</sup> at 110°C for .5 hour, reducing the pressure and recovering the resultant gel liquor; filtering the gel liquor through a stainless steel screen of 100 mesh, recovering the filtrate by adding water to the residue and repeating 3 times; drying, including pouring the filtrate on dry plates and placing in an oven set at 50°C +/- 3°C; recovering gelatin that is slightly yellowish and transparent flakes after the gel liquor is dried to a moisture content below 10%; pulverization of the gelatin with a hammer crusher into a powder sizing 80-200 mesh; packaging the powder including vacuum packaging after it passes quality control.

However, Harnack discloses a process of making gelatin where after the collagen is subjected to hydrolyzation with an acid, the stock is washed to remove excess acid and to adjust the pH [col. 1, lines 47-51] to about 5.5. to 7.5 [col. 3, lines 23-25], where gel liquor resulting from heating of collagen in the conventional method is removed, filtered, and subsequently dried [col. 2, lines 9-12] then comminuting the dried collagen by using a hammer mill making it capable of passing through a 100 mesh screen [col. 5, lines 30-34] as discussed above. Hadden discloses a process where collagen is subjected to 115°C to 125°C in a pressure cooker and subsequently

Art Unit: 1794

gelatinized [col. 9, lines 1-4] when held at 100°C for 4 hours (this time is under regular cooking conditions and not pressure cooking conditions) [col. 9, lines 1-14] and also discloses where the collagen material is hot air dried on a tray within a temperature range of 45°C to 55°C to a moisture content of less than 10% [col. 3, lines 15-20, 47-49]. The NOSB-TAP discloses the characterization of gelatin products as colorless or slightly yellow, and transparent and odorless and (brittle) dry [pg. 2, Properties]. Phillips discloses where the extraction of the gel liquor is repeated 3 to 5 times by adding hot water to the residue and then removing the liquor and filtering after the 3 to 5 extractions have been completed [pg 67]. Robson discloses using a 100 mesh screen to filter fibrous material to achieve the desired clarity [col. 4, lines 40-43; col. 3, lines 57-60]. McGuckian discloses vacuum packaging a food product after it passes quality control [col. 1, lines 5-9; col. 2, lines 45-49].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Taylor, Harnack, "NOSB-TAP", Hadden, Phillips, Robson, and McGuckian before him or her to modify the process of Taylor to include washing the material to a pH of 5.5. to 7.5 in order to stop the hydrolyzation reaction caused by the addition of the acid and to neutralize the material. It would have been obvious to subject the collagen to 115°C to 125°C in a pressure cooker and then to reduce the pressure applied to the material before recovering the gel because the application of heat causes gel formation and the application of pressure reduces gel formation time and further it is well known in the art to reduce the pressure on a pressure cooker before opening to remove the contents since failing to do so would

Art Unit: 1794

cause an explosion. Although Hadden does not explicitly state a "stainless steel jacketed pressure cooker" it is well known in the art that pressure cookers are made from stainless steel or aluminum and that using a jacketed pressure cooker would have been advantageous to use in an industrial setting. Further regarding the time for the heat/pressure treatment, Hadden discloses 4 hours under normal atmospheric conditions; however it is well known in the art that heating materials, to a desired consistency, under pressure is accomplished in a reduced amount of time as compared with atmospheric heating. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the time needed for the heat/pressure step for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272. Further regarding temperature, Hadden discloses the heating temperature at 115°C to 120°C, however, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the temperature for the intended application, since the material is being heated under pressure and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

It would have been obvious to filter the gel liqueur in order to remove insoluble materials and to aid in the ease of the drying process as discussed above and to add water 3 to 5 times to the residue in order to obtain a higher quality gelatin of greater clarity [Phillips pg 69]. It would have been obvious to then use a 100 mesh filter in order

Art Unit: 1794

to filter out the undesired particles and to provide a golden clear liquid [Robson col. 3, lines 57-59].

It would have been obvious to hot air dry the gelatin on a tray within a temperature range of 45°C to 55°C to and a moisture content of less than 10% in order to produce a strong food grade gel ["NOSB-TAP" pg 2; Philips pg 69-70].

It would have been obvious that an acid treated, heat/pressure treated, and subsequently filtered gel as done in conventional collagen processing would recover a gelatin product that would have been characterized as being colorless or slightly yellow, and brittle (dry) and odor free as found in all gelatin products.

It would have been obvious to pulverize the gelatin with a hammer mill (synonymous with a hammer crusher) into a powder sizing 100 mesh in order to obtain a dried gelatin product having a finer gelatin particle size as discussed above.

It would have been obvious to package the powder including vacuum packaging after it passes quality control in order to ensure the inhibition of bacterial growth, properties, and shelf life [col.2, lines 36-41] of the gel.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FELICIA C. KING whose telephone number is (571)270-3733. The examiner can normally be reached on Mon- Thu 7:30 a.m.- 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m. alternate Fridays off.

Art Unit: 1794

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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